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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 09/242,700   | 04/19/1999  | NORIKO MIZOBUCHI     | 20-4518P              | 1380             |
| 2292   | 7590        | 03/07/2003           |                       |                  |
| BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      | EXAMINER              |                  |
|  |             |                      | GOLLAMUDI, SHARMILA S |                  |
|  |             |                      | ART UNIT              | PAPER NUMBER     |
|  |             |                      | 1616                  |                  |

DATE MAILED: 03/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                       |                  |
|------------------------------|-----------------------|------------------|
| <b>Office Action Summary</b> | Applicant No.         | Applicant(s)     |
|                              | 09/242,700            | MIZOBUCHI ET AL. |
|                              | Examiner              | Art Unit         |
|                              | Sharmila S. Gollamudi | 1616             |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 10 December 2002.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 14,18 and 21-25 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 14,18 and 21-25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

The Request for Continued Examination and Extension of Time received on December 27, 2002 are acknowledged. Claims 14, 18, and 21-25 are included in the prosecution of this application. Claims 1-6, 8-10, 15, 17, and 19-20 are cancelled.

### ***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 18, and 21-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Instant specification support the definition of hydrocarbon gel as defined in Japanese Pharmaceutical Excipients submitted in Paper No. 22. The examples in the specification define the hydrocarbon gel as Japanese Pharmaceutical Excipient, however there is no support that both are indeed are same as asserted since applicant has not defined the gel in the originally filed specification.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claims 14, 18, 21-22 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Konishi et al (5,916,918).**

Konishi et al disclose an ointment containing 2g acetylsalicylic acid and 98g plastibase (example 14).

\*Note that the slight amount of ethanol is evaporated to yield a composition consisting of acetylsalicylic acid and a hydrocarbon gel only.

**Claims 14, 18, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 62267232.**

JP discloses a composition containing 5% aspirin and petrolatum.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konishi et al (5,916,918).**

Konishi et al disclose an ointment containing 2g acetylsalicylic acid and 98g plastibase (example 14). The reference teaches the use of different bases for ointments such as white Vaseline (col. 3, lines 8-11).

Konishi do not exemplify Vaseline.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Vaseline as the ointment base in the composition since Konishi et al teach its suitability in the composition. One would be further motivated to do so with the expectation of similar results since both are hydrocarbon compounds.

**Claims 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 62267232 by itself or in view of Takashima et al (4,794,107).**

JP discloses a composition containing 5% aspirin and petrolatum.

JP does not specify if the petrolatum is white or yellow.

Takashima et al teach an ointment. The reference teaches higher paraffin hydrocarbons such as liquid paraffin, white petrolatum, and yellow petrolatum are conventionally used in preparation of ointments (col. 2, lines 24-34).

In the absence of showing the criticality of using white petrolatum versus yellow petrolatum, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to use either in the composition. One would be motivated to do so with the expectation of similar results since both are hydrocarbon based and similar properties. Further one would be motivated to use one versus the other depending on availability and desired color (yellow versus white) result of the composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Takashima et al's teachings since the reference teaches the conventional use of either white or yellow petrolatum. One would be motivated to do so with the expectation of similar results since Takishima teaches that white and yellow petrolatum both are higher paraffin hydrocarbons and have similar properties.

**Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 62267232 or in view of Chang (4,164,563).**

JP discloses a composition containing 5% aspirin and petrolatum.

JP does not teach the use of a hydrocarbon gel.

Chang teaches a non-greasy composition for topical use. The reference teaches examples of suitable solid petrolatum such as Vaseline and Plastibase (hydrocarbon base).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a hydrocarbon gel or petrolatum interchangeably in the composition. One would be motivated to do so with the expectation of similar results

since Chang teaches the both Vaseline and Plastibase are examples solid petrolatum with similar properties.

**Claims 14, 18, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2144326.**

GB discloses an ointment containing acetylsalicylic acid and a hydrocarbon base of beeswax and paraffin (Note example 1). GB teaches the base should be anhydrous and compatible with the acetylsalicylic acid. Suitable bases taught are liquid paraffin, lanolin, white soft paraffin (white petrolatum), white beeswax, hard paraffin, and mixtures thereof (page 1, lines 67-75).

GB does not exemplify a composition without beeswax.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of the prior art with the guidance of the art. One would be motivated to remove beeswax from the composition since GB teaches a mixture of anhydrous bases may be used or a single base without changing the composition since the criticality of the prior art's composition and instant invention lies in the absence of water from the composition.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

MGH

March 5, 2003



MICHAEL G. HARTLEY  
PRIMARY EXAMINER